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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,230	11/09/2001	John Tallman	99,130-H	3200

7590

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/045,230

Applicant(s)

TALLMAN ET AL.

Examiner

Michael Brannock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 and 36-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-35 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on n/a is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 120902, 020503.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Applicant's timely election (June 8, 2004) of Group III is noted. However, after further consideration, a new restriction requirement is issued below.

#### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to methods of screening compounds for cognitive enhancing activity, classified in class 436, subclass 501.
- II. Claims 12-23, drawn to methods of screening compounds for hypnotic activity, classified in class 436, subclass 501.
- III. Claims 24-35, drawn to methods of screening compounds for anxiolytic activity, classified in class 436, subclass 501.
- IV. Claims 36-47, drawn to methods of screening compounds for antidepressant activity, classified in class 436, subclass 501.
- V. Claim 48, drawn to methods of marketing a drug with hypnotic activity, classified in class 725, subclass 705.
- VI. Claim 49, drawn to methods of marketing a drug with anxiolytic activity, classified in class 725, subclass 705.
- VII. Claim 50, drawn to methods of marketing a drug with antidepressant activity, classified in class 725, subclass 705.

The inventions are distinct, each from the other because of the following reasons:

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Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-IV are directed to methods that are distinct both physically and functionally, e.g. they require different animal models of distinct aspects of physiology, and are not required one for the other. Group I requires methods of screening compounds for cognitive enhancing activity, which is not required by any of the other groups. Group II requires methods of screening compounds for hypnotic activity, which is not required by any of the other groups. Group III requires methods of screening compounds for anxiolytic activity, which is not required by any of the other groups. Group IV requires methods of screening compounds for antidepressant activity, which is not required of any of the other groups. Further, although a search of one method may overlap that of another, the searches would not be coextensive; a search of any one of the methods could not be relied upon to provide art that is anticipatory of any other method.

Although the inventions of Group II and Group V are directed to methods and not products, they are related essentially as subcombination (Group II) and combination (Group V).

Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because one would expect that a drug identified by the method Group II would also be identified by conventional methods of finding hypnotic drugs, thus the

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additional elements gaining regulatory approval and marketing do not require the particulars of the subcombination element. Further the subcombination has separate utility such as to identify compounds to be used solely for research purposes to study the role of the different GABA receptor subtypes. Further a search of both of these inventions would not be coextensive and considerably burdensome, as evidenced by their separate classification in the art. The same reasoning applies to the inventions of Groups III and VI and to Groups IV and VII.

The following inventions are unrelated because the use of one is not required for the use of the other:

Group V is not related to any of Groups I, II, IV, VI, and VII

Group VI is not related to any of Groups I, II, IV, V, and VII

Group VII is not related to any of Groups I-III, V, and VI

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

During a telephone conversation with Steven Sarussi on September 2, 2004 a provisional election was made without traverse to prosecute the invention of Group III, claims 24-35 and 49. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-23, 36-50 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen-L, et al., WO 98/19165.

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The invention of the instant claims is predicated on the idea that selective activation GABA  $\alpha 2\beta\gamma 2$  receptors, while minimizing activation of receptors having  $\alpha 1$  subtype, will produce anxiolytic effects with minimal sedative and cognitive impairing effects, see pages 33-39.

Jensen-L, et al. teach this principle, see the Abstract and also teach an assay that measures the *in vitro* efficacy of a compound and the affinity of the compound on  $\alpha 2\beta\gamma 2$  receptors and comparing these parameters of the compound toward receptors having the  $\alpha 1$  subtype, and choosing the compound that is selective for the  $\alpha 2\beta\gamma 2$  receptor, see claim 8. This claim differs from the instant claims in several insignificant ways. Jensen does not teach any particular  $EC_{50}$ , e.g. that the  $EC_{50}$  be less than 200 nM as in the instant claim 24. One of ordinary skill in the art of pharmacology would not need to be taught a particular number to use as this would readily be apparent during routine optimization of operating parameters. Further, claims 34 and 35 require the additional steps of measuring the selectivity *in vivo* and Jensen do not discuss this. However, as the object of the assay of Jensen is to identify agents that would be useful for *in vivo* use, it would be obvious to one of ordinary skill in the art to additionally measure the *in vivo* efficacy using the old and well established models of anxiety and sedation.

### ***Conclusion***

No claims are allowable

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-

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0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D., can be reached at (571) 272-0961.

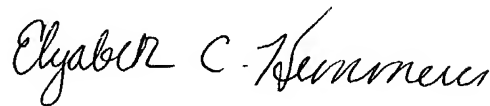
Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



September 3, 2004



ELIZABETH KEMMERER  
PRIMARY EXAMINER